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March 24, 2004

Via electronic mail and via regular mail

David W. Feigal, M.D., MPH, Director
Center for Devices and Radiological Health (HFZ-410)
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20057

Re: Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy (Docket No. 01N-0067)

Dear Dr. Feigal and Docket: Manager:

Please find attached a Supplemental Request for Referral to An Advisory Committee filed by Consumers for Dental Health. We would be happy to provide any additional information on this issue, and can be contacted at the number above.

Sincerely,

Charles G. Brown

Charles G. Brown, national counsel
brownchas@erols.com

cc:
Linda Kahan, Deputy Director, and
Susan Runner, DDS
Les Weinstein, Ombudsman
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Capitol Hill Staffers

01N-0067 SUP 5

To: Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20057

Re: *Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy (Docket No. 01N-0067)*

SUPPLEMENTAL REQUEST FOR REFERRAL TO AN ADVISORY COMMITTEE

I. Background

On February 20, 2002, the Food and Drug Administration ("FDA") published a proposed rule in the Federal Register entitled, "Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy" (the "Proposed Rule"), 67 FR 7620. In the Proposed Rule, the FDA announced its intent to take three actions: 1) issue a separate classification regulation for encapsulated mercury intended to be mixed in a single-use capsule to form filling material for the treatment of dental caries (a pre-amendments device that was never classified) to deem it a class II device; 2) amend the classification for amalgam alloy (a class II device) to add certain special controls; and 3) reclassify dental mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth from (currently a class I device) to class II. See id. Specifically, FDA proposed that certain regulatory guidance and voluntary consensus standards be applied to dental amalgam, including: ingredient labeling; storage and handling instructions; specifications and test methods for determining product composition; and packaging and marketing recommendations. Id. at 7627-7628.

FDA sought public comment on the Proposed Rule. As discussed below, in September 2002, Consumers for Dental Choice submitted their comments regarding the Proposed Rule. Those comments identified specific problems with the Proposed Rule, provided references to scientific information regarding the potential health risks associated with the use of dental amalgam, and formally requested that FDA convene a new, balanced advisory committee to address many of the issues raised in the Proposed Rule.

II. FDA Frequently Has Used Its Authority to Seek Review of Scientific and Regulatory Issues by Outside Advisory Committees

Over the years, FDA frequently has sought advice from outside experts on a wide array of topics--from BSE to product approvals to food biotechnology--using both its standing advisory committees as well as ad hoc committees created for a specific purpose. FDA currently has 32 standing advisory committees, including the Medical Devices Advisory Committee, which was established in 1990 and includes a Dental Products Panel. Outside experts often provide not only additional resources, but also scientific or other expertise, and a fresh and balanced perspective on regulatory issues that the Agency may have been dealing with for a long time. Advisory committees are an important tool that the Agency has to further examine important issues before it, and FDA has ample precedent for such use.

Therefore, it is entirely appropriate for FDA to utilize an outside advisory committee for the review of the many important scientific and regulatory issues raised by the Proposed Rule, including: the classification of medical devices, the use of performance standards and controls, and the data regarding the health and safety risks that dental amalgam poses to patients.

III. FDA Should Refer the Important Scientific and Regulatory Issues Raised by the Proposed Rule to An Advisory Committee

On May 23, 2002, Consumers for Dental Choice requested the creation of a new Advisory Committee, the sole subject of that filing to the rule. *See* Exhibit A. When the time to comment was enlarged, Consumers for Dental Choice submitted more extensive comments in September 2002, including as the first request for relief (page 10) that an new Advisory Committee be empanelled. *See* Exhibit B. In those comments, Consumers for Dental Choice formally requested that a new advisory committee be created and that meetings be held regarding the dental amalgam issues raised in the Proposed Rule. Presumably, such an advisory committee: 1) would be designated by a charter; 2) would conduct open public meetings, 3) would have an FDA official present at each meeting; 4) would have its meeting agendas approved by a government official; 5) would have official minutes of each meeting; and 6) would make all information under consideration available to the public, to the extent that such information is releasable under the Freedom of Information Act. 5 U.S.C.A. App. 2 §§ 9, 10.

To date, FDA has not convened an advisory committee to address any of the specific issues outlined in the Proposed Rule. Consumers for Dental Choice respectfully submits this supplemental request that FDA convene a new advisory committee, as provided for under 5 U.S.C.A. App. 2 § 1 et seq., to consider whether the Proposed Rule adequately addresses the potential health and safety risks associated with the use of dental amalgam, as well as the following other issues:

- Whether the scientific data regarding the potential health risks associated with dental amalgam warrant a ban on the use of such products in the United States;

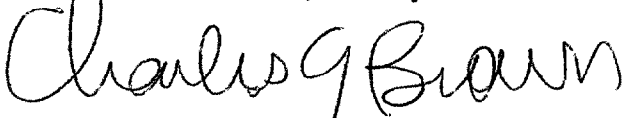
- Whether the scientific data regarding the potential health risks associated with dental amalgam warrant stricter controls on the use of dental amalgam in certain vulnerable populations, including children and pregnant women;

- Whether the special controls contemplated in the Proposed Rule, (e.g. labeling requirements, controls on storage and disposal, and standards for specifications and test methods) are sufficient to protect patients, including children and pregnant women, from the risks of dental amalgam; and

- Whether there are any other, more stringent regulatory controls that FDA could require in order to better protect patients from the potential risks associated with the use of dental amalgam.

As discussed in its previous comments submitted to the Agency, Consumers for Dental Choice believes that, in its current form, the Proposed Rule is deeply flawed. However, Consumers for Dental Choice supports open, public discourse from a balanced panel of experts on these important dental amalgam issues, and believes strongly that referral of these issues to a new advisory committee could provide just that. Therefore, Consumers for Dental Choice reiterates its request that the issues contained in the Proposed Rule be referred to a newly-chartered advisory committee.

Submitted March 24, 2004 by:



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cc: Mary Ann Newell, Vancouver, Washington -- Manager of Rule Docket for Consumers for Dental Choice

(Exhibit A)

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Docket # 01N-0067 - Against FDA Proposal re Mercury Dental Fillings
Submitted to public record: *fdadockets@oc.fda.gov*

May 23, 2002

Dr. David Feigal, Director
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and
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Food and Drug Administration
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Re: Request for New Advisory Panel re Mercury Dental Fillings

Dear Dr. Feigal and Dr. Statland:

I am counsel for Consumers for Dental Choice, Inc. We are informed that a new comment period will soon commence for the proposed rule protecting mercury dental fillings. We would request, and hereby put this request on the public record, that you re-create an Advisory Panel. Because the Panel met so long ago -- eight years, an eon in today's world of constantly emerging science -- we believe our request is grounded not only in fairness and sound public policy, but as a legal requirement as well.

The role of the Advisory Panel is, as you know, critical to writing a rule. You have relied on a panel that met eight years ago. In those eight years, a colossal amount of peer-reviewed studies, policy developments, laws, regulations, trends on mercury dental fillings have emerged – and they are virtually all negative to mercury in dental fillings. This rule blesses mercury dental fillings. It should not. Such fillings belong in a Class III category.

An Advisory Panel is needed to take into account developments such as these, all of which have occurred since it met so long ago:

- The many peer-reviewed studies condemning mercury dental fillings, by Professors Haley, Lorscheider, Vimy, Summers, Aposhian, Chang, etc.;

- The Health Canada report, recommending no mercury fillings for children, pregnant women, and those with kidney problems, braces, or mercury allergies;
- The contraindication warnings by the manufacturer Dentsply, advising dentists to stop giving mercury fillings to children, pregnant women, and those with kidney problems, braces, or mercury allergies;
- The case directing that Proposition 65 warnings (California) issue for mercury dental fillings;
- The ending of mercury in other health care uses, such as in vaccines, thermometers and contact lenses.
- The Watson-Burton bill, H.R. 4163, with five more co-sponsors to date, which would abolish mercury dental fillings;
- State bills, similar to Watson-Burton, introduced in, to date, Alabama, Arizona, California, Georgia, and Illinois.
- The 1999 report of the Agency for Toxic Substance and Disease Registry.
- The resolution of the California Medical Association (2000) favoring phasing out of all health care products that contain mercury;
- The resolution of the American Public Health Association (1999) favoring phasing out of all health care products that contain mercury;
- The official paper of the American Pediatric Medical Association advising physicians to recommend mercury-free dentists to patients concerned about exposure to mercury;
- The emergence of Health Care Without Harm as an organization opposed to mercury in health care products;
- The creation of Consumers for Dental Choice (1996), a consumer group favoring, first, informed consent, and second, an end to mercury dental fillings;
- The creation of the Coalition to Abolish Mercury Dental Fillings (2001), an umbrella group supporting policies ending mercury in dentistry;
- State laws directing specific warnings issue: Arizona (2000), Maine (2001), and New Hampshire (2002);
- The implementation of a 1992 California statute requiring a "fact sheet" on the risks of mercury fillings, so blithely ignored by the Dental Board that the Legislature shut down the Board in 2001;

The constituency make-up of such a panel needs to reflect current realities, not those of a decade ago. Two national consumer organizations need to be consulted about the consumer members – Consumers for Dental Choice, Inc., and Dental Amalgam Mercury Syndrome, Inc., two major consumer groups focused primarily on mercury in dentistry. We hereby request the right to recommend members.

We have no idea from the record when the Advisory Panel met, who was on it, when they had public sessions. Public confidence cannot exist in such a closed environment as existed to formulate this proposed rule.

Dentistry stands alone among health professions in advocating placing mercury in the mouths of children, pregnant women, and others. Many other countries are abandoning mercury dental fillings. We know now that poisonous vapors emanate from

the filling to the rest of the body, including to the developing brains of children, and that mercury goes through the placenta to the developing child. The politically powerful American Dental Association, the chief advocate for mercury, fails to disclose that it receives money from amalgam manufacturers while calling amalgam "safe," and that it does not test the product for safety. The ADA position that mercury fillings are good because they have been used for 150 years is scientifically preposterous, as any scientist at the FDA will recognize. It is time the FDA abandoned its efforts to protect organized dentistry and starts examining the science.

Sincerely,

Charles G. Brown

cc: Joseph M. Sheehan, Chief, Regulations Staff, *fax 301-594-4795; jms@cdrh.fda.gov*
Dr. Susan Runner, Branch Chief, Dental Devices, Division of Dental Infection Control and General Hospital Devices, *fax 301.480-3002*
Public record: *fdadockets@oc.fda.gov*

(Exhibit B)

From Consumers for Dental Choice, Inc.

For both Dockets: Dkt #01-D-0064 AND Dkt #01-N-0067

Against FDA Proposal that Covers Up Risks of Mercury Dental Fillings

We object to the FDA proposed rule on substantive and procedural grounds. The rule needs to be retracted and re-written. A new Advisory Panel must be created and hold public meetings.

Mercury, the most toxic non-radioactive element and volatile heavy metal, is now being removed from every use in the human body[1] (save one, dental fillings). An intense debate now divides dentistry on whether amalgam fillings are safe, but about the toxicity of mercury there is no such debate. Mercury dental fillings are toxic when they go into the body, and a hazardous waste when they come out! And when they are in the body, vapors constantly emanate from the fillings, a particular hazard for the developing brains of children.[2]

The FDA has condemned mercury in other health uses, e.g., in fish, in vaccines, in disinfectants, even in products or medicines for horses. It has chosen, uniquely, to call mercury dental fillings safe. The FDA has no basis to separate mercury in dental fillings from other uses, and in fact can cite no peer-reviewed studies, aye not one, which says mercury fillings are safe. The FDA's first rationale, as it recites in its myriad letters to Members of Congress, is the scientifically preposterous claim that it is safe because it has been used for 150 years.

The FDA chose to be highly selective in what it cites. It ignores scientific studies that show the huge health risks of mercury fillings. It ignores state statutes calling for consumer protection – in California, Arizona, and Maine as of February 2002, more since -- and ignores resolutions such as that by the National Black Caucus of State Legislators. When the source has information adverse to the FDA position, the FDA mischaracterizes, or even falsifies that information. For example, the FDA claims, falsely, that Sweden opted for mercury-free dentistry for environmental reasons, when in fact it was for health and environmental reasons, as the record demonstrates. The FDA trivializes the enormously important Health Canada and its recommendations that children and pregnant women not receive mercury fillings, instead relying upon a less important provincial report. The FDA even ignored the highly salient at the largest mercury amalgam manufacturer, Dentsply, put on its MSDS back in 1997 that mercury fillings are

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[1] (1) Mercurochrome and merthiolate, disinfectants, are banned. (2) The CDC has directed that a mercury-based preservative (thimerosal) be removed from childhood vaccines and over-the-counter cosmetics/drugs (ex. contact lens solution). (3) Mercury thermometers are now banned in many states, e.g., California. (4) The American Public Health Association, the California Medical Association, and Health Care Without Harm have all called for the elimination of putting any mercury-based products into the human body.

[2] Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, Toxicological Profile in Mercury, (Update) (1999).

contraindicated for children, pregnant women, and persons with kidney problems or braces. With the tiniest amount of due diligence – or by turning to sources other than those supplied by the American Dental Association – the FDA could have found these facts and put them in its findings.

The FDA ignores the voluminous 1999 report of the Public Health Service -- Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, Toxicological Profile in Mercury, (Update) (1999) -- which says that mercury from dental fillings can harm the brain, and is of highest risk to children getting mercury fillings (because their brains are just developing "children are not little adults," the report notes). It further notes that the mercury goes through the placenta to the developing fetus, and through the breast milk into the suckling infant. The report states that mercury toxicity is a major health problem, and that the two primary sources of mercury exposure (except for exposed workers) are mercury dental fillings and fish. The FDA is quite concerned about mercury in fish, but AWOL when it comes to the other major source, dental fillings.

The FDA has chosen to side with organized dentistry, its lone supporter in saying mercury fillings are safe, and against the children of America.

A growing movement in both the scientific and dental communities now condemns amalgam. The government of Canada advised in 1996 against its use for (1) pregnant women, (2) children, and people with: (3) kidney problems, (4) braces, or (5) mercury allergies. Indeed, the major manufacturer of amalgam warned back in 1997 that amalgam is contraindicated for those five vulnerable population categories (again, including children and pregnant women).

Peer reviewed studies continue to point to the risks of amalgam.[3]

Dentistry is divided on the issue. The American Dental Association still supports its use, but its scientific basis is specious. First, its main basis is "we have done the procedure for over 150 years," an anti-scientific statement if there ever was one. Second, dentistry can point to no peer-reviewed studies showing mercury fillings are safe, instead citing the platitudes of government agencies who have done no research but relied on the ADA, who has done no research either on amalgam's safety. Third, the ADA gets money from amalgam manufacturers for endorsing the product, a position condemned as unethical by the American MEDICAL Association. (For years, the ADA also held patents on amalgam further evidence of its economic-based support for the product.) Fourth, dentistry uses a deceptive word for the product, something medicine also condemns. Fifth, dentistry gives no warnings about the product (even for allergic patients), something that medicine, again, always tried to do (e.g., penicillin).

Several national dental societies are adverse to the ADA, strenuously opposing placing mercury into human bodies.[4] The California Medical Association adopted a resolution in 2000 urging the abandonment of all mercury-based products. The American

[3] For a listing of the many scientific studies, see www.altcorp.com/amalgmpage.htm, and www.home.earthlink.net/~berniew1.

[4] The International Academy of Oral Medicine & Toxicology, the American Academy of Biological Dentistry, the Holistic Dental Association.

Pediatric Medical Association adopted a similar, albeit less specific, position in an official paper released in 2001.

Congresswoman Diane Watson (Calif.) and Congressman Dan Burton (Ind.) have introduced legislation to phase out mercury-based dental fillings over five years, and stop their use immediately for children, pregnant women, and nursing mothers. The bill, H.R. 4163, would give health warnings between now and the phase-out of the product. Co-sponsors currently include five more Members of Congress: Conyers (Mich.) J. Carson (Ind.), J. Davis (Va.), Ford Jr. (Tenn.), and Hinchey (NY). Similar bills have been introduced in several states, including Alabama, Arizona, California, Georgia, Illinois, and Ohio. Consumer disclosure laws were recently adopted in Maine and New Hampshire, and earlier in Arizona and California.

I. The Advisory Panel met too distantly in the past to consider the emerging science about the health risks of amalgam.

Dusted off from old files, the rule was launched without regard to the science of the past seven years. The FDA took an Advisory Panel report from 1993-94 – eight years is not just old in science, it is ancient. The agency makes a stab at perusing some of the literature since 1993, but misinterprets or misses entirely anything not to its liking.

Since 1994, an amalgam manufacturer, Dentsply, has said amalgam is CONTRAINDICATED for children, pregnant women, and people with braces, kidney problems, or mercury allergies. The government of Canada has recommended that dentists in that country not place such fillings in any of those categories – children, pregnant women, and those with kidney problems, braces, or mercury allergies. That such spectacular developments would escape the attention of the FDA shows the need for a new advisory panel.

An important federal report, to which the FDA gave short shrift, is by the Agency for Toxic Substances and Disease Registry, U.S. Public Health Service: Toxicological Profile in Mercury, (Update) (1999). The report addresses the extreme harm of mercury toxicity, and says its two main causes are fish and mercury dental fillings, or mercury dental fillings and fish (except for employees in a mercury-intensive work environment). The chief victims, the report says, are children, because their brains are still developing, and because the vapors from mercury dental fillings go first to the brain. At extreme risk, too, are children still in the womb, because the mercury goes through the placenta, and also nursing children, because the mercury goes through the mother's breast milk. Small wonder that the populations needing immediate protection from having mercury dental fillings are children, pregnant women, and nursing mothers.

Meanwhile, no peer reviewed studies – none, zero, nada -- since 1994 point to amalgam's safety.

To rely upon an Advisory Panel from the early 1990s is both negligent and plain legal error.

II. There is no record that the Advisory Panel membership meets statutory requirements. Even if so, the Panel does not reflect today's reality of (1) consumer groups opposed to mercury amalgam, (2) diversity and dissension within dentistry, and (3) opposition in the scientific community.

The record needs to note the members and background of the Advisory Panel.

A panel should include representatives of consumers who have organized to oppose mercury dental fillings. Over the past decade, two broad-based consumer organizations have emerged who should be included in any consideration of the issue : Consumers for Dental Choice, Inc. (headquartered in Washington, DC), and Dental Amalgam Mercury Syndrome, Inc. (Minneapolis). More recently, a new umbrella coalition has been formed, the Coalition to Abolish Mercury Dental Fillings. The case law requires that such organizations should be invited to nominate members.

An ongoing petition by consumers seeks to ban amalgam. We incorporate it by reference. http://www.PetitionOnline.com/mercury/petition.html.

The Advisory Panel should be constituted recognizing that (according to the Utah-based Christiansen Institute) 28% of dentists are mercury-free, and which therefore includes dentists drawn from any of the following organizations: International Academy of Oral Medicine and Toxicology (headquartered in Orlando, Fla.); American Academy of Biological Dentistry (Carmel, Calif.), and/or Holistic Dental Association (Steamboat Springs, Colo.). The above report states that the growth of mercury-free dentists has gone from 3% in 1985 to 9% in 1995 to 28% in 2001. Dentists (but not the ADA) are increasingly recognizing the health risks TO THEM of using mercury fillings. One indication: dentists have the highest suicide rate of any profession.

The ADA has even admitted to even more startling data – fewer than 50% of all fillings are now mercury fillings. That too argues for composing a committee of more than zealots for mercury.

Scientists who have studied this issue – e.g., Professor Haley, Professor Aposhian, Professor Summers, Professor Lorscheider, Dr. Vimy, Dr. Hanson – should be included if the panel is to meet legal standards and have scientific and public credibility.

III. There is no record of public meetings or hearings of the Advisory Panel.

The regulation should list the activities of this Advisory Panel. We have no way of ascertaining its functions, particularly since it met in the distant past. The public has a right to view these meetings. That they were done in a distant past means, with the emerging and overwhelming consumer interest today in this issue, new meetings should be held.

IV. The report ignores the emerging science.

The scientific developments against using mercury amalgam fillings have been overwhelming in the past decade. We have attached some of the many studies. In addition, we incorporate into the record by reference three web sites that contain hundreds of sources: www.altcorp.com/amalgmpage.htm; www.home.earthlink.net/~berniew1; and http://www.vimy-dentistry.com/.

Attached is a summary of 20 peer-reviewed studies. It is disappointing that the FDA staff either failed to notice them or chose to ignore them (we are not sure which would be more disappointing). We have also attached many studies in notebooks. Finally, here is a listing of a few of the many books covering the health risks of mercury dental fillings: (1) Levenson, Dr. Jack, Menace in the Mouth. Brompton Health, London, Sweden: 2000; Stortebecker, M.D., Ph.D., Patrick. Mercury Poisoning from Dental Amalgam: A Hazard to Human Brain. Bio-Probe, Orlando, Florida: 1985; (2) Hardy, Dr. James E., Mercury Free: The Wisdom Behind the Global Consumer Movement to Ban "Silver" Dental Fillings. Gabriel Rose Press, Inc., U.S.A.: 1996; (3) Huggins, Dr. Hal A., It's All in Your Head: The Link Between Mercury Amalgams and Illness. Paragon Press, Honesdale, Pennsylvania: 1993; (4) Queen, H.L. Your Personal Health Guide: The Secret to Gaining & Maintaining Health. Queen and Company Health Communications, Inc., Colorado Springs, Colorado: 1997; (5) Queen, H.L., Chronic Mercury Toxicity: New Hope Against an Endemic Disease. Queen and Company health communication, inc., Colorado Springs, Colorado: 1988; (6) Ziff, Sam and Dr. Michael F. Ziff, D.D.S. Dentistry Without Mercury. Bio-Probe, Inc., Orlando, Florida: 2001; (7) Ziff, Sam and Dr. Michael F. Ziff. Infertility & Birth Defects: Is Mercury from Silver Dental Fillings an Unsuspected Cause? Bio-Probe, Inc., Orlando, Florida: 1987; (8) Atkins, M.D., Robert C., Dr. Atkins New Diet Revolution. Avon Books Inc., New York, New York: 1992; (9) Brown J.D., Ellen Hodgson and Richard T. Hansen, D.M.D., The Key to Ultimate Health. Advanced health Research Publishing, Fullerton, California: 1998.

We have included in the record the following book of *case studies*: Davis, Mary. Solving the Puzzle of Mystery Syndromes: Are Your Amalgam Fillings the Missing Piece? Hott Off The Press Printing Co., Des Moines, Iowa: 2000. The regulation falsely asserts that all that can happen when a person becomes mercury toxic from dental fillings is an allergic reaction – it is the least problem when we are discussing a bioaccumulative neurotoxin like mercury. This report, of real people with real life stories, belies the claim of the FDA / ADA that all consumers have to worry about with mercury is skin rashes!

Basically, the FDA sets out to prove amalgam is safe. Such a result-oriented approach to science is bound to fail

- Amalgam is 43 to 54% mercury.
- No peer-reviewed studies say it is safe
- Numerous peer review studies say it has risks
- Case studies – a report is attached -- say it is highly risky
- Other governments have issued warnings or entire phase-outs of its product
- No peer-reviewed studies say it is safe. To rely upon one government agency quoting another, which cites 150 years of use as a "scientific" basis, is outrageous, both in science and in public policy.

V. The FDA proposal severely limits public input.

The FDA compounds the problem by doing all it can to rush through this rule. It is conducting no public hearings. It has no period to respond to the comments of other responders. It invited the public to comment via e-mail – the only sure way to get mail through to the government after 9/11 – then listed a *web site* instead of an e-mail address. Only the most technically proficient (those under age 21) could get through. Consumers and dentists had to find an e-mail address, at the 11th hour, to make submissions. Clearly, many more submissions would have been made with a proper e-mail listing.

Even the ADA admits the issue is now a public controversy. It asked such a question in a poll it just published, and found that 60 percent of the public is still unaware of the "health controversy" (the ADA's words) over amalgam. The FDA pretends what even the ADA no longer does – that the matter is one of public controversy. It is time this rule-making was done in the public domain and both sides were presented within the Advisory Panel and in the proposed regulation. This one-sidedness defies current science, public policy, and the emerging intense public debate.

We have requested a 60-day extension for public comment. That request is pending.

VI. The FDA is rushing through this proposal.

The proposal came on the heels of an announcement by Congresswoman Watson that she would introduce legislation seeking to ban amalgam. After the rule was proposed, she introduced the bill, joined by co-sponsors Congressmen Burton, Ford, Hinckley, and McGovern, and Congresswomen Carson and Davis (H.R. 4163).

The proposal also came amidst a flurry of proposals at the state level to provide consumers disclosures or to ban dentists from performing the procedure on children.

The American Dental Association opposes all such bills, even those advocating disclosure.

The FDA did nothing for a decade, despite repeated petitions. Then, it acted based on old data and an outdated Advisory Panel, with no public hearings, and no rebuttal opportunity. Since the proposal mirrors the position of organized dentistry totally, it is fair to surmise that the FDA is acting only in response to, and to counter, developments opposed by the American Dental Association.

VII. The rule is a bailout for the American Dental Association.

The FDA rule so closely mirrors the economic agenda of the American Dental Association that we are frankly concerned about the agency's independence from this special interest organization.

The rule pretends that the agency "inadvertently" failed to classify the amalgam mixture. Actually, the agency did so intentionally, in order to "pass the buck" to dentists on the safety question. Now that dentists are being sued for failure to warn patients, or

for harming children and pregnant women by putting mercury in their bodies, the FDA rule seeks to exonerate the dentist by declaring, retroactively, that the FDA meant to do things differently. The FDA doesn't even proffer an explanation of its "inadvertence."

The ADA has a huge vested interest in protecting the marketing of amalgam:
-- Through its Seal of Acceptance program, the ADA quietly takes thousands of dollars from amalgam manufacturers, then declares amalgam to be safe and effective. In fact, the ADA has never determined amalgam to be safe. It has never done a peer reviewed study that shows amalgam to be safe. It trumpets the wonders of amalgam in its trade magazines, the Journal of the American Dental Association and ADA News, but neither is a peer-reviewed journal.
-- For years, the ADA had patents on amalgam. The patents have now expired.
-- Both the money taken from amalgam manufacturers and the patents constitute a brazen conflict of interest by the ADA. The American Medical Association has a strict policy against taking money for product endorsements, because the practice is unethical, according to the AMA. The ADA has no such ethical qualms.
-- The failure of the ADA to note its revenue from amalgam manufacturers, and its patents before they expired, while endorsing amalgam, constitutes a deception on the public.
-- Using amalgam is great dental economics, as it allows the dentists to place the maximum number of fillings per hour and thus make more money that fillings that take time to mold in the mouth. The ADA policies, and the FDA regulation, put in place a system of protective dental economics instead of public protection.
-- The ADA has been sued for such practices. The FDA rule attempts to shield the ADA by declaring amalgam to be safe.
-- It is increasingly likely that many dentists will be sued for failing to disclose the risks of amalgam. This rule constitutes a shield for them, rather than providing information to the public.

VIII. The FDA appears to be attempting to pre-empt state consumer protection laws.

Among the most disappointing aspects of this proposal is the term "uniform disclosure," which would infer an FDA effort to pre-empt state consumer protection laws and bills. Note that the FDA did not act when there was an absence of state laws – it acted amidst a flurry of bills. California passed a law in 1992, but it was never implemented by the state Dental Board. Arizona passed a law in 2000, but with the same non-result. In 2001, state legislative activity heated up:

- The California Legislature shut down the Dental Board for failing to implement the Watson law, requiring disclosures of the risks of mercury fillings.
- The Maine Legislature passed a tough disclosure bill.
- The Arizona Legislature, through its budget bill, demanded compliance with the law enacted in 2001.

The FDA proposal does not even note the existence of the laws in California (1992), Arizona (2000), and Maine (2001). Surely the FDA knows of these laws. Their passage was constantly referenced in ADA materials, apparently the only literature the FDA appears interested in reading. To ignore the existence of such laws, while calling

for "uniform" disclosures, is another attempt to hide important information that belongs in the public record.

But it is this year, on the heels of the federal proposal by Congresswoman Watson, that put the mercury-free movement on the political map. Bills were introduced in several states to phase out its use, or for consumer disclosures, including (sponsor name in parentheses) California (Assemblyman Dickerson), Washington (Lieutenant Governor Owen), Arizona (Representative Brimhall), Alabama (Representative Rogers, et al.) Georgia (Representative Holmes, et al.), Illinois (Representative Flowers), and New Hampshire (Representative Lynde). The New Hampshire bill has been enacted into law. In addition, the Maine Legislature enacted a law to implement the law it passed the year before.

Predictably, the ADA (in *ADA News*) referenced this FDA regulation (even though it is not enacted) as a basis to invalidate the Dickerson bill in California, A.B. 2270. The ADA is obviously so confident that the FDA will enact the mirror of its own position that it is touting the regulation as being in force and effect.

Does the FDA plan to pre-empt? If so, it should say so, boldly, instead of hiding the ball on its intentions.

IX. The regulation is punitive to lower-income and minority families.

As Americans wise up to the reality that "silver" fillings are really "mercury" fillings, they are converting to alternatives. Unfortunately, the "they" does not include families in Medicaid or families on limited insurance plans. Most third-party payment systems have a policy of "mercury fillings or no fillings." For low- and moderate-income Americans, there is in reality no choice.

The origin of the system of paying only for mercury fillings lies with the American Dental Association. Delta Dental Plan was created by the ADA, and historically controlled by dentists in most states. Delta Dental set the pace: insure for the ADA's favorite filling material: mercury.

The FDA could lead the way to transitioning of third-party payment systems (government and private), by issuing proper warnings. Payment plans could evolve into paying for the slightly higher-priced filling material, as the State of Maine is doing right now. A law on informed consent is leading Maine toward paying for alternatives for Medicaid patients. (*Bangor Daily News*, May 20, 2002).

X. The proposal contains factual errors and is intellectually dishonest.

For example, the proposal says that mercury is classified as Class II when it is currently Class I. The proposal says Sweden and other countries adopted anti-amalgam policies for environmental reasons, when health reasons were also important.

More important than its specific errors is the overall intellectual dishonesty of the proposal. It pretends that the scientific literature favors mercury fillings, when the only favorable reporting is by agencies who make vague claims mirroring the ADA position, and when the scientific literature is against mercury in all uses. It pretends state laws do not exist. It ignores manufacturer warnings, Proposition 65 enforcement actions, legal actions, and any other material adverse to the ADA. It is a Pollyannaish tribute to one of the most toxic elements and the most volatile heavy metal.

XI. The Proposal Does Not Provide the Specific Warnings that Will Issue.

After its apology piece for mercury amalgam, the proposal fails to state with specificity what warnings will issue on each product, and how. Forcing the public to comment in May, then facing an October surprise on a finalized rule, is unfair to all concern, and fails to provide the specificity required in rule-making.

XII. Because of the widespread consumer deception, the FDA must be especially vigilant in its warnings.

Organized dentistry has a two-part strategy to keep consumers from learning that mercury is the main component of amalgam, and that its use is highly controversial. First, the ADA promotes the fillings as "silver" fillings, a not surprising step considering that the term "mercury" fillings would draw attention from most parents, and could hurt the ADA's future payouts from amalgam manufacturers. The public understandably believes the fillings are "silver." Indeed, the ADA boasts about a recent survey that 60% of the public is unaware of the mercury controversy.

Second is the ADA gag rule, as enforced by state dental boards. By enjoining dentists from initiating warnings to their patients, the ADA and the dental boards maintain a silence that keeps the public from learning even that the fillings are mercury, and about health risks as well. The American Civil Liberties Union challenged the Oregon gag rule, successfully, as did the Goldwater Center in Arizona. In many other states, however, the gag rule remains.

In this circumstance, the FDA must take extraordinary steps to override a conspiracy of silence and get the health warnings out. Instead, the FDA takes the opposite approach: disclose nothing, and override those states who are trying to provide warnings!

XIII. Amalgam should be classified as Class III.

There is one category, and one alone, to which amalgam belongs: Class III. The scientific literature we and others submit make that clear.

The FDA has no place in comforting or confirming a medical practice simply because it has been used for a long time. Amalgam products are constantly new and remade; there is no "grandfathering" issue here. It is time the FDA abandons politics and economics, and returns to its legislative mission of protecting American consumers.

Amalgam is a Class III product. The issue is not a close call.

SUMMARY

We hereby request

- A new Advisory Panel be empanelled, to review the science of the past seven years.
- An extension period for public comment.
- A right to reply to the comments of organized dentistry, who submitted platitudes from other government agencies instead of peer-reviewed science.
- A public hearing.

We request a total re-writing of the rule, one that includes the following:

- A clarification of the preemption question concerning state laws and regulations.
- A description of what the disclosure will actually say, so that we may comment specifically.
- A proposal devoid of factual errors.
- An explanation of the "inadvertent" failure to classify, an event of over a decade ago that was never addressed until now, and which is addressed without explanation.
- A rule that contains scientific research negative to amalgam.

We request that any final rule which issue

- Classify amalgam as a Class III substance, or
- Prohibit amalgam for children, pregnant women, nursing mothers, and people with braces, and provide strong warnings for all others.

Respectfully submitted,

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